K072475

SECTION 5 – 510(k) SUMMARY

Submission Correspondent:	Emergo Group, Inc.
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Submission Sponsor:	Etac Sverige AB SE-165 41 Kista, Sweden Tel: +46.8.633 47 00 Fax: +46.8.653 18 70 www.etac.com
Date Prepared:	August 17, 2007
Trade Name(s):	(1) Balder Finesse Powered Wheelchair (2) Balder Junior Powered Wheelchair
Common/Usual Name:	Powered Standup Wheelchair
Classification Name:	Wheelchair, Stand-up
Classification Number:	890.3900
Classification Panel:	Physical Medicine Devices
CDRH Product Code:	IPL
Regulatory Class:	II
Description:	The Balder Finesse and Balder Junior powered wheelchairs are front-wheel driven power wheelchairs that have been designed and developed to be used in both indoor and outdoor environments, and to transport one (1) person at a time. The

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wheelchairs are outfitted with a seat lift, so that its user can reach objects on high shelves as well as slide their legs under the table when seated. The Balder Finesse and Balder Junior powered wheelchairs can also be purchased with a stand-up function option that allows the user to be placed in a stand-up position, thus allowing them to operate the wheelchair while standing.

The Balder Finesse and Balder Junior powered wheelchairs operate using an electric, front-wheel drive motor that is driven by two (2) 12 Volt, 52 Amp dry cell batteries, and contains a D.C. permanent magnet type motor that uses graphite-copper brushes with integrated brakes (12/24V).

The wheelchair frame is of welded steel construction and includes the rear castor wheels, front driving wheels with drive motor (i.e., motor, gear, brakes) and batteries. The motor controller, with joystick, can be mounted on either the left or right armrest depending on the user's needs.

The motor controller, with joystick and software that is found in each wheelchair is manufactured by Dynamic Controls, a division of Invacare Corporation, and was previously cleared by the FDA on May 12, 1997 (see K970094).

Intended Use:

The Balder Finesse and Balder Junior stand-up powered wheelchairs by Etac are indoor/outdoor battery operated multifunctional wheelchairs. The intended use of these powered wheelchairs is to provide mobility to persons that have the capability of operating a powered wheelchair.

Predicate Devices:

1. LEVO Comfort II (K051387); Wheelchair (IPL)
2. DX Micro Computer Control for Power Wheelchairs (K970094); Controller (ITI)

Safety and Effectiveness:

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and different technological characteristics. But, it can be

demonstrated that the device is as safe and effective as the predicate device and the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device.

As such, it has been shown in this 510(k) submission, that the differences between the Balder Finesse and Balder Junior stand-up powered wheelchairs by Etac and the predicate device, the LEVO Comfort II (K051387), do not raise any questions regarding their safety and effectiveness.

The Balder Finesse and Balder Junior stand-up powered wheelchairs by Etac as designed are as safe and effective as the predicate device and therefore are determined to be substantially equivalent to the referenced predicate device.

Performance Data:

The Balder Finesse and Balder Junior stand-up powered wheelchairs by Etac have been designed, manufactured and tested for conformance to the applicable ISO and EN standards as referenced in this submission. In addition, the Balder Finesse and Balder Junior stand-up powered wheelchairs passed all required consensus standards testing for conformance to the FDA's *Guidance Document For the Preparation of Premarket Notification [510(K)] Applications For Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Etac Sverige AB
% Emergo Group, Inc.
Mr. Ian Gordon
Senior Vice President
1705 Capital of Texas Highway, Suite 500
Austin, Texas 78746

Re: K072475
Trade/Device Name: Balder Finesse and Balder Junior
Regulation Number: 21 CFR 890.3900
Regulation Name: Standup Wheelchair
Regulatory Class: Class II
Product Code: 89IPL
Dated: November 29, 2007
Received: December 03, 2007

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: Balder Finesse and Balder Junior

Indications for Use:

The Balder Finesse and Balder Junior stand-up powered wheelchairs by Etac are indoor/outdoor battery operated multifunctional wheelchairs. The intended use of these powered wheelchairs is to provide mobility to persons that have the capability of operating a powered wheelchair.

Prescription Use _____X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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